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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,879	06/27/2003	Lieven Stuyver	2551-123	5237

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/606,879	STUYVER ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32 and 34* is/are pending in the application.

4a) Of the above claim(s) *18-27,30-32 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,28 and 29* is/are rejected.

7)☒ Claim(s) *15-17,28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

Restriction election

2. The Office acknowledges the amendment filed on September 18, 2006. Claim 33 is cancelled. Claims 15-32 and 34 are pending.

3. The Office acknowledges the receipt of Applicant's restriction election filed on September 18, 2006. Applicant elects, with traverse, Group I, Claims 15-17, 28 and 29. Applicant further elects the single species of SEQ ID NO: 77 for purposes of initial examination.

4. The traverse is on the ground that the subject matter of Groups I-VI has not attained separate status in the art so as to define separately patentable independent and distinct inventions as evidenced by the since they have the same class and subclass. Applicant requests withdrawal of the restriction requirement and search and examination of at least all of the subject matter of the Group I-VI are requested (Paragraphs 3 and 4, Remarks).

5. Applicant's traversal is unpersuasive for the following reasons: The PTO classification is merely an administrative convenience and is not dispositive of relatedness of inventions. While a search of the prior art for one group may overlap with that of another group, the search are not co-extensive and thus would be an undue burden on the Office resources even if the Groups were placed in the same class and subclass.

6. In response to Applicant's request to search and examination of all of the subject matters

of the Group I-VI, the examiner has pointed out in the previous Office action, that the subject matters of Groups I-VI are subcombinations, usable together. According to MPEP 806.05(d), the examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Since Applicant does not prove or provide an argument, supported by facts, that the other use, suggested by the examiner, cannot be accomplished or is not reasonable (see MPEP 806.05(d), the requirement is still deemed proper and is therefore made FINAL.

7. Accordingly, Claims 15-32 and 34 are pending. Claims 18-27, 30-32 and 34 are nonelected. Claims 15-17, 28 and 29 are examined in the instant Office action.

Specification

8. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Drawings

9. The following informality has been noted in the drawings submitted on February 9, 2004. It is note that not all claimed SEQ ID NOs are labeled in Figure 1. Applicant is required to add all claimed SEQ ID NOs in Figures 1A-IV. It is also note that the nucleic acid numbers of HBV

genomes are missing in Figures 1B, 1G, 1H, 1N, 1T and 1V. Corrections and formal drawings are required in response to this Office Action.

Information Disclosure Statement

10. The information disclosure statement, filed on June 27, 2003, fails to completely comply with 37 CFR 1.98(b)(5) because some cited references listed under other documents lack the titles of the publications (See MPEP 609). The information referred to therein has not been considered. The US and foreign patent documents have been considered.

Claim Objection

11. Claims 15-17, 28 and 29 are objected. An article "A" should be placed in the beginning of Claim 15. A definite article "The" should be placed in frond of "Method according to..." of Claims 16, 17, 28 and 29.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonough (EP0569237A2, 1993).

14. Claims 15 and 16 are directed to a method for determining the presence or absence of

HBV genotype A in a biological sample, **comprising:** (i) optionally releasing, isolating and/or concentrating the polynucleic acids present in the sample; (ii) optionally amplifying the HBsAg region, or part thereof, of the HBV gene present in said sample with at least one suitable primer pair; (iii) hybridizing the polynucleic acids of step (i) or (ii) with at least one nucleotide probe of about 5 to 50 nucleotides long hybridizing specifically to a HBV genotype A specific target sequence in the HBsAg region of HBV; (iv) detecting the hybrid(s) formed in step (iii); (v) inferring the HBV genotype present in said sample from the hybridization signal(s) obtained in step (iv), wherein the HBV genotype A specific target is selected from the group consisting of SEQ ID NOs: 279-313.

15. McDonough teaches a method of detecting of HBV subtype A, such as HBV*adw*, using amplification oligonucleotides and hybridization probes. McDonough's method comprises the step of amplifying HBV with oligonucleotides primers, and the step of hybridizing HBV nucleic acids obtained directly or amplified HBV nucleic acids. McDonough also specifies the method is used for detecting HBV genotype A, HBV*adw* (see pp 11 and 12).

16. Since McDonough's method meets the limitations of Claims 15 and 16, the instant Claims 15 and 16 are anticipated by McDonough.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

> patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 15-17, 28 and 29 are rejected under 35 U.S.C. 103(a) as being obvious over McDonough, Maertens (WO 94/12670) and Ashton-Rickard (1989).

19. Claims 15-17, 28 and 29 are directed to a method for determining the presence or absence of HBV genotype A in a biological sample, comprising: (i) optionally releasing, isolating and/or concentrating the polynucleic acids present in the sample; (ii) optionally amplifying the HBsAg region, or part thereof, of the HBV gene present in said sample with at least one suitable primer pair; (iii) hybridizing the polynucleic acids of step (i) or (ii) with at least one nucleotide probe of about 5 to 50 nucleotides long hybridizing specifically to a HBV genotype A specific target sequence in the HBsAg region of HBV; (iv) detecting the hybrid(s) formed in step (iii); (v) inferring the HBV genotype present in said sample from the hybridization signal(s) obtained in step (iv), wherein the HBV genotype A specific target is selected from the group consisting of SEQ ID NOs: 279-313, wherein step (iii) is a reverse hybridization step, wherein the HBV genotype A specific target sequence is selected from the group consisting of SEQ ID NO: 77, SEQ ID NO:140 and SEQ ID NO:193, or the complement thereof, wherein the primer is selected from the group consisting of SEQ ID NOs: 75-76, 94, 105, 112 and 134-135. Applicant has elected SEQ ID NO: 77 for provisional examination. SEQ ID NO:77 is corresponding to codons 142-147 of HBsAg as indicated in Figure 1D of specification.

20. Maertens teaches a line probe assay (LiPA) for genotyping viruses, such as HCV, HIV, HBV and/**or** HTLV present in biological samples (see P. 25). Maertens teaches the method comprises the steps of providing at lease one of the probes of HCV and at least of one of the

probes capable of detecting HIV, and/**or** HBV, and/**or** HTLV, possibly providing a set of primers to respectively amplify HIV, and/**or** HBV and/**or** HTLV by means of PCR, contacting the biological sample with the probes under conditions which allow hybridization between the probes and target sequences. Maertens specifically indicates that the invention also relates to a method for determining the type or subtype of any other parenterally transmitted viral isolate such as HTLV, HIV, HBV characterized by incorporating on one and the same strip, probes hybridizing specific to the HCV, HIV-1/2, HBV mutants or HBV core, pre-core (see p. 26). Maertens teaches that the probes are immobilized in a line-wise fashion to a membrane strip for reverse hybridization.

21. Maertens does not explicitly teach SEQ ID NO:77, which is corresponding to specific codons 142-147 of HBV, as a target sequence of HBV genotype A. Maertens does not teach primers of SEQ ID NOs: 75, 76, 94, 105, 112 134, and135.

22. Ashton-Rickardt teaches immunodominant regions of HBV subtypes. Ashton-Rickardt teaches that antigenic regions of HBsAg are defined for different subtypes of HBV, such as *a*, *d* or *y* antigens. The *a* group (HIV genotype A) are is located between amino acid residues138-147. The region determining *b* or *y* antigenic specificity has been placed between residues 110 and 139 of HBsAg (Introduction, p. 196).

23. The relevance of McDonough is set forth *supra*.

24. It would have been obvious to one of ordinary skill in the art to use the hybridization method for detecting the presence of HBV genotype A in a biological sample as taught by Maertens and McDonough. One would have been motivated to do so and would have been a reasonable expectation of success, given the knowledge that line probe assay can be used to

genotype HCV, HIV, HBV and/**or** HTLV, as taught by Maertens, and also given the knowledge that The *a* group (HIV genotype A) is located between amino acid residues 138-147, as taught by Ashton-Richardt. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to make the claimed primers/probes because primer design is a routine practice for one of skill in biological laboratories. Following a few known general principles such as the primer length, complexity, the G+C content and optimized melting temperature, etc., will ensure success. Therefore, given the availability of known HBV sequences from databases, the knowledge of antigenic regions of HBV subtypes, one of ordinary skill in the art would have had a reasonable expectation of success in designing and making the claimed primers. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

25. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bruce Campell

Bo Peng, Ph.D.
12/7/06

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